## DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

## PROCESSING IN STEAM-AIR RETORTS

(Retort Survey)

## **INSTRUCTIONS**

Complete the question blocks below. Draw a diagram of the retort or obtain one from the firm. Attach the diagram as an exhibit to the EIR. Report all pipe sizes as inside diameter (ID). Cross-sectional area =  $3.14r^2$  (r =  $\frac{1}{2}$  diameter).

If problems are found with the firm's retort equipment or processing system, refer the reader to the narrative Turbo EIR under "Objectionable Conditions and Management's Response," and include a narrative explanation of specific problems and evidence under the subheading "Supporting Evidence and Relevance." Submit the completed form as an EIR attachment.

Steam-air retorts are covered by 113.40(j) – "Other Systems" and must meet the requirements found in applicable sections of 113.40. The retorts and operating procedures must be carefully evaluated to insure that they comply with Part 113.

Some of the questions in this form are designed to capture information useful in evaluation of the retort system and may not indicate a deviation from LACF Regulations, Part 113. The FDA "Guide to Inspections of Low Acid Canned Foods, Part 2" should be used as a guide when conducting inspections of steam-air retort systems.

Steam-air retorts are made by a variety of different manufacturers. They are normally horizontal batch type still or rotary end-over-end retorts. Steam-air has been used in some installations as the heating medium in continuous rotary, hydrostatic and hydrolock retorts. Photographs are an excellent means of enhancing the description of a retort system.

RETORT DESCRIPTION				
RETORT NO.	TYPE OF RETORT	LENGTH OR HEIGHT	DIAMETER	
	Vertical Horizontal			
	Other			
RETORT MANUFACTURER:				
RETORT MODEL:				
TEMPERATURE RANGE OF	THERMAL PROCESS (E.G., 245/250	)/260 DEGREES F):		
NUMBER OF BASKETS OR	CRATES PER RETORT:			
PROCESSING MODE:	Static Still	Agitating	Axial Rocking	
	IONS INSIDE THE RETORT OR THE DING/UNLOADING OF CRATES?			
	COMPUTER	CONTROLS		
DOES A COMPUTER CONTI	ROL ANY OF THE RETORT FUNCTION	DNS?	Yes  No	
DOES THE FIRM HAVE DOO	CUMENTATION ON HAND THAT INDIC	CATES THAT THE COMPUTER SY		
EXPLAIN:			Yes ∐ No ∐	
IS RECORD KEEPING PART	OF THE COMPUTER FUNCTION?		Yes	

IF YES DOES THE RECORD KEEPING COMPLY WITH 21 CFR PART 11?
AGITATION
IS THE AGITATING RETORT OPERATED IN THE STILL MODE?
HAVE PROCESS ESTABLISHMENT TESTS DETERMINED THAT RETORT CRATE POSITION IS CRITICAL TO THE PROCESS OR COME UP PROCEDURE?
IF 1ES, DESCRIBE THE CHATE POSITION RECOMMENDED BY THE PROCESS AUTHORITY.
HOW DOES THE FIRM DETERMINE CRATE POSITION?
WAS THE RECOMMENDED CRATE POSITION BEING USED DURING THE INSPECTION?
EXPLAIN HOW THE RETORT ROTATION SPEED IS DETERMINED:
EXPLAIN HOW THE RETORT ROTATION SPEED IS RECORDED:
STEAM-AIR MIXTURE
WHAT IS THE PROCESSING PRESSURE USED DURING THERMAL PROCESSING? (NOTE IF SEVERAL DIFFERENT PROCESSING TEMPERATURES ARE USED; PLEASE NOTE THE PRESSURE AT EACH TEMPERATURE. IF THE FIRM PROCESSES DIFFERENT CONTAINER TYPES, PLEASE NOTE THE PRESSURE FOR EACH CONTAINER TYPE.)
WHAT IS THE PERCENT STEAM/AIR MIXTURE USED DURING PROCESSING:
(NOTE: % STEAM CAN BE DETERMINED BY DIVIDING THE STEAM PRESSURE POUNDS PER SQUARE INCH ACTUAL BY THE TOTAL SYSTEM PRESSURE.)
E.g., 10 PSI (generated by temp of 240 degrees F) + 14.7 PSI Atmospheric pressure = 24.7 = 83% steam  15 PSI gauge reading on retort + 14.7 PSI Atmospheric pressure = 29.7 (24.7/29.7 x 100 = 83%)
HOW IS STEAM ADDED TO THE RETORT?
IS THE STEAM SPREADER OR OTHER SYSTEM IN A GOOD STATE OF REPAIR?
DESCRIBE THE LOCATION WHERE COMPRESSED AIR IS ADDED TO THE RETORT:
IS THE COMPRESSED AIR HEATED PRIOR TO BEING ADDED TO THE RETORT?
IS A DIFFUSER USED ON THE AIR ENTRY TO INSURE MIXING OF THE AIR AND STEAM?

HAS THE AREA WHERE AIR ENTERS THE RETORT BEEN IDENTIFIED AS A COLD SPOT IN THE RETORT? Yes \( \subseteq \text{No} \subseteq \)
HOW IS PRESSURE CONTROLLED IN THE RETORT?  Set Pressure Relief Valve   Card Reader   Computer Program   Analog Controls   Other   EXPLAIN:
DOES THE FIRM HAVE DOCUMENTATION WHICH INDICATES THE PERCENT AIR OR AIR PRESSURE PARAMETERS CRITICAL TO THE THERMAL PROCESS?
DOES THE FIRM MONITOR AND RECORD RETORT PRESSURE DURING PROCESSING?
IF A PRESSURE GAGE IS PRESENT, IS IT GRADUATED IN DIVISIONS OF 2 LBS. OR LESS?
DO THE PRESSURES NOTED MEET THOSE ESTABLISHED BY THE TEMPERATURE DISTRIBUTION STUDIES?  Yes No EXPLAIN:
DOES THE FIRM HANDLE DEVIATIONS FROM PROCESSING PRESSURES AS PROCESS DEVIATIONS? Yes No EXPLAIN:
WHAT METHOD IS USED TO MIX THE STEAM AND AIR?Fan Bleeders Other DESCRIBE:
IS WATER OR CONDENSATE ADDED TO THE STEAM AIR MIXTURE?
HOW DOES THE FIRM INSURE THAT THE FAN IS OPERATING?  Indicator Light  Computer Monitoring  Visual Inspection  DESCRIBE INSPECTION FREQUENCY:
MERCURY IN GLASS THERMOMETERS/TEMPERATURE INDICATING DEVICES
IS THE RETORT EQUIPPED WITH A MIG THERMOMETER?
IS THE RETORT EQUIPPED WITH ANOTHER TYPE OF TEMPERATURE INDICATOR DEVICE? IF SO, DESCRIBE THE INDICATOR

ARE SCALE DIVISIONS EASILY READABLE TO 1°F (.5°C)?
NO. OF DEGREES F OR C/IN. OF GRADUATED SCALE: (TEMP. RANGE MUST NOT EXCEED 17°F(8°C) PER INCH (4°/CM) OF GRADUATED SCALE – 113.40(a)(1). ALSO, SEE LACF GUIDE, P. 14.)
DATE TEMPERATURE INDICATING DEVICE LAST TESTED FOR ACCURACY:
STANDARD USED FOR THE TEST:
NAME AND TITLE OF PERSON WHO PERFORMED TEST:
IS THE LAST TEST DATE IDENTIFIED ON THE TEMPERATURE INDICATING DEVICE?
DESCRIBE THE FIRM'S ACTIONS REGARDING MIG THERMOMETERS/TEMPERATURE INDICATORS THAT WERE OUT OF CALIBRATION:
IS THE MIG THERMOMETER MERCURY UNDIVIDED?
WHEN TEMPERATURE INDICATING THERMOMETERS ARE FOUND TO BE PROVIDING READINGS ABOVE THE ACTUAL TEMPERATURES, DOES THE FIRM EVALUATE PRODUCTS PRODUCED USING THOSE THERMOMETERS? Yes No DESCRIBE THE FIRM'S PROCEDURES: (NOTE IF THE ACTUAL TEMPERATURE IS BELOW THAT REQUIRED BY THE SCHEDULED THERMAL PROCESS, THIS WOULD BE A PROCESS DEVIATION AS PER 113.89.)
IS THE TEMPERATURE INDICATING THERMOMETER LOCATED WHERE IT IS EASY TO READ ACCURATELY?  Yes  No
THE SENSOR BULB IS LOCATED IN THE
DIAMETER OF OPENING TO EXTERNAL WELL:
HOW DOES THE FIRM INSURE THAT THE TEMPERATURE MEASURED IN THE WELL IS REPRESENTATIVE OF THE TEMPERATURE IN THE RETORT SHELL?
TEMPERATURE RECORDER
TYPE OF TEMPERATURE RECORDER:
IS THE TEMPERATURE CHART ADJUSTED TO AGREE AS NEARLY AS POSSIBLE WITH BUT NOT HIGHER THAN THE KNOWN ACCURATE MERCURY-IN-GLASS THERMOMETER DURING THE PROCESSING PERIOD?

NOTE ANY DIFFERENCE BETWEEN THE RECORDING THERMOMETER AND THE MERCURY-IN-GLASS THERMOMETER AND WHICH READING IS HIGHER:
IS THERE A MEANS FOR PREVENTING UNAUTHORIZED ADJUSTMENTS?
IS THE CHART DRIVE TIMING MECHANISM ACCURATE?
IS THE RECORDER COMBINED WITH A STEAM CONTROLLER?
THE TEMPERATURE SENSING BULB IS INSTALLED IN THE
AUTOMATIC STEAM CONTROLLER
IS THE STEAM CONTROLLER AUTOMATIC?
IS THE STEAM CONTROLLER TEMPERATURE ACTUATED?
REPORT THE MANUFACTURER, MODEL, TYPE AND SIZE OF THE AUTOMATIC STEAM CONTROL VALVE:
IF THE TEMPERATURE (STEAM) CONTROLLER IS AIR OPERATED, DOES THE SYSTEM HAVE AN ADEQUATE FILTER TO ASSURE A SUPPLY OF CLEAN, DRY AIR?
COME UP PROCEDURE
DOES THE FIRM USE A STEAM BYPASS DURING COME UP?
DOES THE FIRM (VENT) PURGE AIR FROM THE RETORT PRIOR TO THE THERMAL PROCESS?
DESCRIBE THE PROCEDURES USED BY THE FIRM TO BRING THE RETORT UP TO OPERATING TEMPERATURE:
CAN THE FIRM DOCUMENT ALL STEPS OF THE COME UP PROCEDURE?

DOES THE FIRM IDENTIFY PROCESS COME UP STEPS AS CRITICAL ON THE PROCESS FILING FORMS?	
Yes \( \square\)	lo 🗌
(NOTE: PROCESSING STEPS ARE REQUIRED ON THE PROCESS FILING FORM WHEN THEY HAVE BEEN IDENTIFIED AS CRITICAL TO THE THERMAL PROCESS.)	S
HEAT/TEMPERATURE DISTRIBUTION	
DOES THE FIRM HAVE ON HAND TEMPERATURE DISTRIBUTION DATA OR OTHER SUITABLE INFORMATION THAT DEMONSTRATES THAT HEAT DISTRIBUTION IN THE RETORT IS ADEQUATE?	lo 🗌
EXPLAIN AND PROVIDE COPIES OF SUPPORTING DOCUMENTS:	
DATE OF LAST TEMPERATURE DISTRIBUTION STUDY:	
NOTE: THE FOLLOWING PARAMETERS (RETORT INSTALLATION, COME UP PROCEDURES, CONTAINER TYPE, CONTAIN SIZE, CONTAINER POSITION, PRODUCT TYPE, OPERATING PRESSURE, CRATE AND RACK DESIGN, AND PARTIAL LOA MAY OR MAY NOT EFFECT TEMPERATURE DISTRIBUTION IN THE RETORT. ANY FACTOR, THAT CAN INFLUENCE THE MIXING OF STEAM-AIR IN THE RETORT, CAN POTENTIALLY HAVE AN EFFECT ON TEMPERATURE DISTRIBUTION IN TH RETORT.	DS)
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH INDIVIDUAL RETORT? Yes 🗌 N	lo 🗌
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH CONTAINER SIZE?	lo 🗌
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH CONTAINER TYPE <i>(E.G., GLASS, METAL,</i> PLASTIC)	lo 🗌
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH CONTAINER HOLDING ARRANGEMENT/ RACKING SYSTEM USED BY THE FIRM?	lo 🗌
HAS A TEMPERATURE DISTRIBUTION STUDY BEEN PERFORMED ON EACH INDIVIDUAL PRODUCT OR PRODUCT TYPE (E.G., SEAFOOD SOUP VERSUS CANNED TUNA)	:? lo 🗌
DID EACH TEMPERATURE DISTRIBUTION STUDY IDENTIFY A COLD SPOT IN THE RETORT?	lo 🗌
HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED TO DETERMINE THE EFFECTS OF TEMPERATURE DROPS DURING COME UP AND PROCESSING?	lo 🗌
HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED TO DETERMINE THE EFFECTS OF PRESSURE DRO DR EXCESS PRESSURE IN THE RETORT?Yes NREPORT RESULTS:	PS lo 🗌
ARE PARTIAL LOADS PROCESSED IN THE FIRMS RETORTS?Yes N	lo 🗌
ARE BAFFLE PLATES OR DUMMY LOADS USED DURING THE PROCESSING OF PARTIAL LOADS?Yes NEXPLAIN:	lo 🗌

DESCRIBE THE RETORT CRATES. DIMENSIONS: NUMBER OF HOLES: SIZE OF HOLES: LOCATION OF HOLES: LOCATION OF HOLES: LOCATION OF HOLES: ARE CONTAINERS POSITIONED IN THE RETORT AS SPECIFIED IN THE SCHEDULED PROCESS?	HAVE TEMPERATURE DISTRIBUTION STUDIES BEEN PERFORMED WITH PARTIAL LOADS?	Yes 🗌	No 🗌
DIMENSIONS:  NUMBER OF HOLES:  SIZE OF HOLES:  LICCATION OF HOLES:  LOCATION OF HOLES:  LOCATION OF HOLES:  ARE CONTAINERS POSITIONED IN THE RETORT AS SPECIFIED IN THE SCHEDULED PROCESS?	RETORT CRATES, RACKS		
NUMBER OF HOLES:  SIZE OF HOLES:  LOCATION OF HOLES:  ARE CONTAINERS POSITIONED IN THE RETORT AS SPECIFIED IN THE SCHEDULED PROCESS?	DESCRIBE THE RETORT CRATES.		
SIZE OF HOLES:  LOCATION OF HOLES:  ARE CONTAINERS POSITIONED IN THE RETORT AS SPECIFIED IN THE SCHEDULED PROCESS?	DIMENSIONS:		
ARE CONTAINER PROCESSED WITHOUT DIVIDER PLATES?  ARE CONTAINER PROCESSED WITHOUT DIVIDER PLATES?  DESCRIBE STACKING ARRANGEMENT (E.G., BRICK OFFSET, JUMBLE):  DOES THE FIRM PROCESS?  Metal Cans	NUMBER OF HOLES:		
ARE CONTAINERS POSITIONED IN THE RETORT AS SPECIFIED IN THE SCHEDULED PROCESS?	SIZE OF HOLES:		
ARE DIVIDERS, TRAYS, RACKS OR OTHER MEANS OF POSITIONING FLEXIBLE CONTAINERS DESIGNED AND EMPLOYED TO INSURE EVEN CIRCULATION OF HEATING MEDIUM AROUND ALL CONTAINERS?	LOCATION OF HOLES:		
INSURE EVEN CIRCULATION OF HEATING MEDIUM AROUND ALL CONTAINERS?  ARE DIVIDER PLATES USED?  DESCRIBE NUMBER OF HOLES AND DISTRIBUTION IN DIVIDER PLATES:  IS THE SAME TYPE OF DIVIDER PLATE USED FOR ALL CONTAINERS?  DESCRIBE DIFFERENCES:  ARE CONTAINERS PROCESSED WITHOUT DIVIDER PLATES?  DESCRIBE STACKING ARRANGEMENT (E.G., BRICK ,OFFSET, JUMBLE):  IS CONTAINER NESTING POSSIBLE?  HOW DOES FIRM CONTROL NESTING OF CONTAINERS?  DOES THE FIRM PROCESS?  Metal Cans	ARE CONTAINERS POSITIONED IN THE RETORT AS SPECIFIED IN THE SCHEDULED PROCESS?	Yes 🗌	No 🗌
DESCRIBE NUMBER OF HOLES AND DISTRIBUTION IN DIVIDER PLATES:  IS THE SAME TYPE OF DIVIDER PLATE USED FOR ALL CONTAINERS?			
IS THE SAME TYPE OF DIVIDER PLATE USED FOR ALL CONTAINERS?	ARE DIVIDER PLATES USED?	Yes 🗌	No 🗌
DESCRIBE DIFFERENCES:  ARE CONTAINERS PROCESSED WITHOUT DIVIDER PLATES?	DESCRIBE NUMBER OF HOLES AND DISTRIBUTION IN DIVIDER PLATES:		
DESCRIBE STACKING ARRANGEMENT (E.G., BRICK ,OFFSET, JUMBLE):  IS CONTAINER NESTING POSSIBLE?		Yes 🗌	No 🗌
HOW DOES FIRM CONTROL NESTING OF CONTAINERS?  DOES THE FIRM PROCESS?  Metal Cans		Yes 🗌	No 🗌
Metal Cans		Yes 🗌	No 🗌
Glass Jars			
Pouches			
Rigid Plastic			
LIST ALL CONTAINER SIZES:  METAL CANS –  GLASS JARS –  POUCHES –			
LIST ALL CONTAINER SIZES:  METAL CANS –  GLASS JARS –  POUCHES –	DOES THE FIRM PROCESS MORE THAN ONE CONTAINER SIZE?	Yes 🗆	No □
METAL CANS –  GLASS JARS –  POUCHES –			
GLASS JARS – POUCHES –			
POUCHES -			
- '	RIGID PLASTIC –		

IF MORE THAN ONE CONTAINER SIZE OR TYPE IS PROCESSED AT ONE TIME DESCRIBE PROCEDURE USED:
FOR POUCHES, ARE TRAYS ADEQUATELY DESIGNED WITH POCKETS TO CONTAIN AND RESTRAIN INDIVIDUAL POUCHES DURING PROCESSING?
ARE TRAYS OR DIVIDER PLATES IN GOOD CONDITION WITH NO ROUGH OR SHARP POINTS THAT COULD PUNCTURE CONTAINERS?
CONTAINER COOLING
CONTAINERS ARE COOLED BY:
EXPLAIN CONTAINER COOLING:
EXI EAIN CONTAINEN COCEING.
TYPE OF VALVE ON COOLING WATER LINES:
WERE COOLING WATER LINES NOTED TO BE LEAKING?
WATER DRAINS
ARE SCREENS USED OVER ALL DRAIN OPENINGS TO PREVENT CLOGGING OF DRAINS?
IS THE DRAIN VALVE WATER TIGHT AND NON-CLOGGING?
OTHER CONCERNS AND OBSERVATIONS

PLEASE EXPLAIN ANY OTHER CONCERNS WITH THE OPERATION OF THIS RETORT SYSTEM: